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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/745,243	12/21/2000	Narendra Parikh	JBP514	8350

7590

01/09/2003

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EXAMINER

PULLIAM, AMY E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 01/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/745,243

Applicant(s)

PARIKH ET AL.

Examiner

Amy E Pulliam

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10,11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Supplemental Information Disclosure Statements, received July 8, 2002 and September 30, 2002, as well as the Request for Reconsideration with Attachment, received by the Office October 22, 2002.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 2-53271 to Okada *et al.* in view of US Patent 4,309,405 to Guley *et al.*. [All page citations for Okada *et al.* refer to Applicant's provided translation.] Okada *et al.* disclose a tablet containing coated granules characterized in that the coated granules are further coated by a protective film of water-soluble polymer or of acid-soluble polymer (claim 1). Okada *et al.* teach that it is widely known in the art to use enteric, acid soluble, or insole films to coat granules to hide taste or odor

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and to add various functions such as sustained release (p 2, para 4). The film of the coated particles is comprised of one or two or more of enteric polymers or wax (claim 2). There is an active medicinal drug product contained in the coated granules (claim 3). Additionally, Okada *et al.* teach that the protective film can one of the following, or a mixture of two or more, including HPMC, HPC, MC, PVP, PEG and gelatin (p 2, para 7).

Okada *et al.* do not teach examples of the enteric and insoluble polymers used in the first coating layer.

Guley *et al.* teaches sustained release pharmaceutical compositions. However, the Guley *et al.* reference is relied upon for the teaching of specific insoluble and enteric coating polymers. Guley *et al.* teaches that ethylcellulose is a well known insoluble polymer used in pharmaceutical compositions (c 2, l 45-49). Additionally, Guley *et al.* teaches that well known enteric coating materials include cellulose acetate phthalate, and HPMC phthalate (c 3, l 15-20).

To summarize, Okada *et al.* teach a granule coated with an enteric or insoluble polymer, and then further coated with a polymer or mixture of polymers to prevent breakage. Okada *et al.* suggests the combination of HPMC and PEG as the outer film protective coating. Okada *et al.* does not specify polymers useful in the first coating layer. Guley *et al.* teaches well known enteric and insoluble polymers, for use in coating granules. It is the position of the examiner that one of ordinary skill in the art would have been motivated to look to teachings in the art to provide examples of well known insoluble polymers and enteric coating polymers. Furthermore, it is the position of the examiner that one of ordinary skill in the art would have been motivated to use any of the insoluble polymers discussed by Guley, and any of the enteric polymers disclosed by Guley, in the first coating layer disclosed by JP '721, because JP '721 requires the

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specific types of coatings, but does not give specific examples. The expected result in using one of the polymers specified in Guley as the first coating on the granules discussed in Okada *et al.* would be a successfully coated granule with taste masking, odor masking, or other functional capabilities which aid in sustained release (Okada *et al.*, p 2, para 4). For these reasons, the invention of applicant would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner
Art Unit 1615
January 7, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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